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K113209

Summary of Safety and Effectiveness

Date of Preparation: October 27th 2011

Submitter Information/ production site:

Pajunk GmbH
Karl-Hall-Strasse 01
78187 Geisingen
Germany
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
Establishment Registration Number: **9611612**

Contact:

Christian G. H. Quass
Director Regulatory Affairs, Safety Official
Patricia Weisbrod, *Regulatory Affairs*
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
E-Mail: christian.quass@pajunk.com
E-Mail: patricia.weisbrod@pajunk.com

USA Contact:

PAJUNK MEDICAL SYSTEMS
6611 Bay Circle, Suite 100
Norcross, GA 30071
Phone: (770) 493 - 6832 ext.111
Fax: (678) 514 - 3388
Cell: (770) 330 - 2724
richard.fischer@pajunk-usa.com

Contact

Richard Fischer MD
President
Fon: +01(0)770-493-6832 Ext 111
Fax: 678 5143388
E-Mail: Richard.fischer@pajunk-usa.com

Contract Sterilizer:

Ethylene Oxide;
External service provider, validated procedure.

Device Information:

Device Name:	Needle for puncture/ aspiration/ biopsy
Trade Names:	Chiba SONO, SONO-Series
Common Name:	Soft tissue puncture, aspiration and biopsy instrument
Classification Name	Gastroenterology-urology biopsy instrument
Classification Reference	21 CFR §876.1075, April 1, 2011
Product Code:	KNW
Subsequent Product code	FCG
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Gastroenterology/Urology
Predicate Device:	K063697 SPECIAL SPROTTE, CHIBA, DR STEINHOFF KIT PAJUNK® GmbH Medizintechnologie, Geisingen

Indications for use

PAJUNK®s soft tissue biopsy, puncture and aspiration cannulas and needles are intended for obtaining biopsies from soft tissues, for use in puncturing and for aspiration.

They are not appropriate for bone biopsies.

Device Description:

Chiba SONO cannulas/ needles enhanced for ultrasound visibility are single use sterile and non-pyrogenic devices used to gain entry or puncture the tissue and aspirate soft tissue for biopsy purposes. The needles/ cannulas may be used during all biopsy and puncturing procedures according to the physician´s indication. Additionally fluids for example for fluoroscopy may be injected.

Cannulas/ needles enhanced for ultrasound visibility are standard cannulas/ needles equipped with CornerStone reflectors (cleared in K111374 – SonoPlex STIM) in order to significantly enhance ultrasound visibility.

The cannulas basically consist of stainless steel tubing and an epoxy glued polycarbonate hub.

In order to enhance ultrasound visibility the cannulas are equipped with a special reflector pattern named "CornerStone" imprinted to the cannulas surface. These reflectors are designed to optimally reflect ultrasound waves.

Predicate Devices:

Predicate device with identical indications of use are:

1) K063697 SPECIAL SPROTTE, CHIBA, DR STEINHOFF KIT
   PAJUNK® GmbH Medizintechnologie, Geisingen

The detailed discussion of substantial equivalence can be found in Section 12 of this submission.

Sterilization

The contract sterilizer and the sterilizing process are identical to the process and sterilizer used for all PAJUNK® - manufactured and purchased devices which are already cleared for market or exempt. CornerStone-technique does neither influence sterilization process nor shelf life properties.

Cleaning and Sterilization method, which ensures an SAL of 10^{-6} as well as compliance with limits for chemical burden, bioburden, pyroburden (i.e. LAL) and EtO-residuals as well as shelf life have been validated and are safe and effective.

Efficacy of sterile product´s lifecycle has been validated for a period of 10 years now. Shelf life is set to 5 years.

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Biocompatibility:

All cannulas comply with ISO 10993-1, 2nd and 3rd edition.

The stainless steel tubing of the Sono-needles/cannulas is identical to stainless steel tubing of the needles/cannulas as they were cleared for market in K063697 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The polycarbonate hub of the Sono-needles/cannulas is identical to the polycarbonate hub of the needles/cannulas as they were cleared for market in K063697 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The epoxy resin glue of the Sono-needles/cannulas is identical to the epoxy resin glue of the needles/cannulas as they were cleared for market in K063697 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The optional polymeric NanoLine coating of the Sono-needles/cannulas is identical to the polymeric NanoLine coating of the NanoLine-needles/cannulas as they were cleared for market in K053283 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

Technology Characteristics:

The components are listed in a table in section 11 of this submission. Shelf life and impact of sterilization and storage on the devices has been proven and found to be safe and effective.

Performance Testing

The needles/ cannulas have been subjected to standard testing applicable for all cannulas. Standard testing consists of bending stability and breaking resistance testing as well as of hub-to-needle-bondage testing. Due to technological equivalence the subject device is tested the same way as each cannula is tested at PAJUNK® GmbH Medizintechnologie. There are no special testing requirements defined, neither in incoming and in-process inspection routines nor in final testing.

Conclusion:

The comparison between the predicate devices and the subject device in section 12 of this submission as well as the validated sterilization process and the results of the bench testing and bench marking demonstrates that the proposed devices are substantially equivalent to the predicate devices and identical in technical description to devices already cleared for market and therefore demonstrated to be safe and effective.

Based on the clinical evaluation, the biocompatibility testing and the bench testing conducted, safety and effectiveness as well as efficacy of the Cornerstone -technique is demonstrated for each type of cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Pajunk GmbH
% Mr. Christian G.H. Quass
Director, Regulatory Affairs
Karl-Hall-Strasse 01
78187 Geisingen, Germany

Re: K113209
Trade/Device Name: Chiba SONO Cannulas/Needles Enhance for Ultrasound Visibility
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: October 27, 2011
Received: October 31, 2011

Dear Mr. Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113209

Indications for use

510(k) Number:

Device Name: Chiba SONO cannulas/ needles enhanced for ultrasound visibility

Indications for Use:

PAJUNK®s soft tissue biopsy, puncture and aspiration cannulas and needles are intended for obtaining biopsies from soft tissues, for use in puncturing and for aspiration.

They are not appropriate for bone biopsies.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mXm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113209